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Idaho Board of Pharmacy

NEWS

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Rule Changes

The following are rule changes that were approved in the 2004 legislative session and are now in effect. If your pharmacy is providing medications to long-term care and assisted living facilities you need to pay particular attention to the changes in Rule 156.

152. Reference Library

01. Required Books. The latest edition and supplement(s) of the following: *Idaho Pharmacy Law and Rules*; one (1) of the following current pharmacy references – Facts and Comparisons*, Clinical Pharmacology, Micromedex*; and one (1) other current pharmacy reference of your choice (book or computer diskette).

156. Pharmacies

01. Change of Ownership or Location. In case of change of ownership or location of a pharmacy, the original registration becomes void and must be returned with a new pharmacy application.

02. Annual Report of Pharmacy Employer. Annually, on the date of renewal of registration, the pharmacy employer must notify the [Idaho] Board [of Pharmacy] of the registered pharmacist-manager of the pharmacy and each registered employee-pharmacist and each extern/intern training in the pharmacy, on the place provided on the application. Any change in pharmacist or extern/intern employment must be reported to the Board within five (5) days.

03. Responsible Pharmacist Manager. A non-registered proprietor of a pharmacy shall place in charge of such pharmacy a pharmacist licensed in the state of Idaho who shall be known as "responsible pharmacist manager" and the non-registered proprietor shall immediately report to the state Board of Pharmacy the name of the pharmacist manager.

04. Responsibility of Pharmacist Manager. Responsible pharmacist managers of pharmacies owned by non-registered proprietors are responsible for the management of such stores so far as they are affected by the pharmacy laws. Every part of the establishment coming under the regulation of the pharmacy laws shall be under the full and complete control of such responsible pharmacist manager.

05. Return of Drugs or Other Items. In the interest of public health, drugs, medicines, sickroom supplies, devices and items of personal hygiene shall not be accepted for return by any pharmacist or pharmacy after such drugs, medicines, sickroom supplies, devices and items of personal hygiene have been taken from the premises where sold, distributed or dispensed, except that medications for in-patients of residential or assisted living facilities, licensed skilled nursing care facilities, and hospitals may be returned to the dispensing pharmacy for credit provided the medications are liquid medications that have been supplied in manufacturer sealed containers and remain unopened, or the medications are in unopened "Unit Dose" packaging. In addition, the following conditions set forth in Subsection 156.05.b. below must be satisfied.

a. Unit Dose is defined as medications packaged in individually sealed doses with tamper-evident packaging (e.g., single unit of use, blister packaging, unused injectible vials and ampules).

b. The following conditions must be satisfied:

   i. The medications must be returned with tamper-evident packaging intact and with no evidence of tampering.

   ii. In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity.

   iii. Policies and procedures are followed for the appropriate storage and handling of medications at the facility and for the transfer, receipt, and security of medications returned to the dispensing pharmacy.

   iv. A system is in place to track restocking and reuse to allow medications to be recalled if required.

   v. No controlled substance may be returned except those delivered by Unit Dose on a daily delivery system.

   vi. If the drug is repackaged by the pharmacy, each repackage container must be labeled in accordance with the following (for purpose of this rule, any change from the original manufacturer's packaging prior to delivery of the medication to the hospital or the facility shall be considered repackaging):

      (1) Name and strength of the medications;

      (2) A suitable expiration date which shall not be later than the expiration date on the original manufacturer's container, or one (1) year from the date the drug is repackaged (If a medication that was repackaged and delivered to the hospital or facility is thereafter returned to the pharmacy and subsequently repackaged again, the expiration date hereunder shall not be later than the expiration date used when the medication was initially repackaged.);

      (3) The date medication was repackaged;

      (4) The manufacturer's lot number, expiration date, and identity; and

      (5) The identity of the pharmacist responsible for the repackaging.

If the information required under Subparagraphs (4) and (5) hereof is maintained in the internal records of the pharmacy, those

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requirements may be omitted from the labeling. The labeling requirements of this Subparagraph vi shall apply in addition to the labeling requirements under Section 159.

c. Medications which have been outside the custody and control of the hospital or facility for any reason are not eligible for return. In order to be considered as having been in the custody and control of the hospital or facility, the medications must have been delivered by the dispensing pharmacy directly to the hospital or facility or to an agent thereof who is authorized and qualified to accept delivery, and the medications must then be held by the hospital or facility in an area suitable for storing medications and not accessible to any patients. Once a medication has passed from the hospital or facility storage area to the patient or to the patient's designee for any reason, the medication is no longer eligible for return.

d. Medications otherwise eligible for return under this rule by virtue of their packaging but which have become ineligible for return for any reason must be marked as follows:

   i. Such medications which are released for self-administration by the patient, or for administration outside the hospital or facility premises or which are otherwise released to be taken outside the custody and control of the hospital or facility, shall first be clearly marked and identified "Not Eligible For Return" PROVIDED HOWEVER, the foregoing requirement for marking shall not apply to the daily dose of medication released to a patient on the day such dose is to be administered provided the hospital or facility does not allow any such medication to be returned to the same medication storage area as medications eligible for return.

   ii. Such medications which are received by the hospital or facility from the patient or the patient's representative, and not directly from the dispensing pharmacy, and which are to be stored in the same storage area as medications which are eligible for return, shall first be clearly marked and identified "Not Eligible For Return."

   iii. In the event medications otherwise eligible for return under this rule by virtue of their packaging are discovered to be ineligible for return because they have been outside the custody and control of the hospital or facility, or for any reason, such medications shall be clearly marked and identified "Not Eligible For Return" immediately upon discovery if they are to remain stored in the same storage area as medications which are eligible for return.

e. Each pharmacy and the pharmacist-in-charge thereof shall be responsible for consulting with each hospital or facility from which the pharmacy will accept returns under this Section 156 to ensure that the hospital or facility has an employee or employees who are trained and knowledgeable in the proper storage, use, and administration of medications at the hospital or facility, and to ensure that the hospital or facility has in place and enforces written protocols which will ensure compliance with the conditions necessary to allow returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols as well as the written approval thereof on file in the pharmacy and produce the same for Board inspectors upon request.

f. Each pharmacy and the pharmacist-in-charge thereof which will be accepting returns under this Section 156 shall establish written protocols for the pharmacy which will ensure compliance with this Section 156 for all returns. The pharmacist-in-charge must review and approve protocols. The pharmacy must keep a copy of the protocols as well as the written approval thereof on file in the pharmacy and produce the same for Board inspectors upon request.

06. Damaged Drugs. To sell, offer for sale, barter or give away any drugs damaged by fire or water or by any other means that might affect the potency of the drug is prohibited without first obtaining the written approval of the Board.

07. Dangerous Drugs. Legend, controlled substances, or other limited sale items must be stored in accordance with United States Pharmacopoeia/National Formulary requirements in the prescription area (where prescriptions are compounded, dispensed or filled) and in a manner as to limit access to licensed pharmacists or authorized personnel of that area only. Failure to comply with this requirement shall be prima facia evidence of unprofessional conduct.

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